UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,497	06/27/2002	John C. Reed	066654-0704	2174

41552 7590 08/06/2009

MCDERMOTT, WILL & EMERY
11682 EL CAMINO REAL
SUITE 400
SAN DIEGO, CA 92130-2047

EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
08/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP_Docket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	10/030,497	REED, JOHN C.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-117* is/are pending in the application.

4a) Of the above claim(s) *111-113 and 115-117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-110 and 114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Reed

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/1/2009 has been entered.

2. Claims 89-117 are pending. Claims 1-88 have been cancelled. Due to species election of BAG-1 (see applicant's response filed on 9/23/05), claims 111-113 and 115-117 have been withdrawn from consideration as being drawn to non-elected inventions.

3. Claims 89-110 and 114 are under examination. Claims are examined to the extent that BAG-1 gene encodes BAG-1.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional

application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/350,518 fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Claims 89-110 and 114 are drawn to a method for determining the risk of tumor recurrence or spread in a patient suffering from prostate cancer, and a method for determining a prognosis in a patient suffering from prostate, said method comprising: (a) determining a BAG-1 gene expression level in a cancerous prostate tissue sample form said patient, (b) comparing said BAG-1 gene expression level in said patient to a reference BAG-1 gene expression level, wherein said reference BAG-1 gene expression level being a level of BAG-1 gene expression above which correlates with increased risk of tumor recurrence or spread, or decreased survival, below which correlates with a decreased risk of tumor recurrence or spread or increased survival. The application no. 09/350,518 discloses that for breast cancer patients, high levels of cytosolic BAG-1 protein in breast cancer tissue are associated with longer distant metastasis-free survival (DMFS) and overall survival (OS) (see working examples on pages 32-37). The application no. 09/350,518 does not disclose the correlation between the levels of BAG-1 and DMFS or OS for patients having prostate cancer. The application no. 09/350,518 does not disclose that for prostate cancer patients, high

levels of cytosolic BAG-1 protein in prostate cancer tissue are associated with shorter distant metastasis-free survival (DMFS) and overall survival (OS) (opposite to breast cancer). Therefore, application no. 09/350,518 does not provide adequate written description for the instant claims, and the claims are not entitled to benefit of the application no. 09/350,518. The effective filing date for the instant claims is 7/7/2000.

Rejections Maintained

Claim Rejections - 35 USC § 103

5. The rejection of claims 89-110 and 114 under 35 U.S.C. 103(a) as being unpatentable over Froesch et al. (Proceedings of the American Association for Cancer Research Annual Meeting, March, 1998, 89: 13, print) in view of the teachings of Takayama et al. (Cancer Research 1998, 58: 3116-3131, IDS), Noordzij et al. (J. Urology, 1997, 158: 1880-1885) and Sano et al. (US patent NO. 5,665,539, IDS) is maintained.

Applicants submitted the Declaration of Reed under 37 C.F.R.1.132. The Declaration states that Takayama's reference cited in the rejection is the inventor's (John C. Reed's) own work, and other co-authors worked under Reed's supervision.

The Declaration has been carefully considered but is insufficient to overcome the rejection. As indicated in paragraph 4 above, the effective filing date of the instant claims is 7/7/2002. Takayama's reference (7/15/1998) was published more than one year prior to the effective filing date of the instant claims, and is a prior art under 102(b). As such, the Declaration does not disqualify the Takayama's reference as a prior art.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 89-110 and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froesch et al. (Proceedings of the American Association for Cancer Research Annual Meeting, March, 1998, 89: 13, print) in view of the teachings of Tang et al. (J. Clin. Oncology, 1999, June, 17(6): 1710-1719, IDS), Yawata et al. (Oncogene, 1998, 16:2681-2686, IDS), and Sano et al. (US patent NO. 5,665,539, IDS).

Froesch et al. teach that BAG-1 protein (cytosolic BAG protein) is expressed in all 9/9 prostate cancer cell lines and 51/51 archival prostate tumor specimens, and BAG-1L protein (nuclear BAG protein) is expressed in prostate cancers and enhances androgen receptor function (see abstract and title). Froesch et al teach detection of BAG-1 and BAG-1L proteins using immunobloting, immnohistochemistry and immunoprecipitation.

Froesch et al. do not teach the step of comparing said BAG gene expression level in said patient to a reference gene expression level, wherein the reference BAG-1 gene expression level is a level of BAG-1 gene expression above which correlates with increased risk of tumor recurrence or spread in a first groups of patients compared to a second group of patients, said second group of patients having BAG-1 gene expression

levels below said reference level. Froesch et al. do not teach an immuno-PCR assay. However these deficiencies are made up for in the teachings of Tang, Yawata, and Sano et al.

Tang et al. teach that BAG-1 is overexpressed in the majority of invasive breast carcinomas, and in multivariate analysis, BAG-1 expression was significantly associated with shorter disease-free and overall survival (see abstract, Figures 3 and 4). Tang et al. disclose that patients whose tumors expressed BAG-1 tended to have less favorable clinical outcome (see page 1716, last paragraph). Tang et al. teach detection of BAG-1 protein by immunohistochemistry (see page 1711, column 2), and further comparing the BAG-1 protein expression level between different groups of patients (see Figures 5 and Table 4, for example). Tang et al. disclose that further large scale retrospective and prospective studies are warranted to test the value of BAG-1 expression in guiding the clinical management of invasive breast cancers (see page 1718, column 2).

Yawata et al. teach that prolonged cell survival introduced by overproduction of BAG-1 strongly enhances peritoneal dissemination of human gastric cancer cells *in vivo* (see abstract). Yawata et al. further disclose that overexpression of BAG1 leads to prolonged cell survival of murine melanoma B16 cells, and this enhanced anti-cell death activity promotes their pulmonary metastasis *in vivo* (see page 2682, lines 1-3).

Sano et al. teach detection of a protein using immuno-PCR (see abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to determine the level of BAG-1 expressed in prostate cancer using immuno-PCR, compare the level with a reference level and further

correlate the results with the risk of tumor recurrence, tumor spread and survival in a patient suffering from prostate cancer in view of the teachings of Froesch, Tang, Yawata, and Sano. One would have been motivated to do so because Froesch et al. teach that BAG-1 protein is expressed in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, Tang et al. disclose that BAG-1 may serve as an independent predictive factor in breast cancer prognosis (see page 1715, column 1) and patients whose breast tumors expressed BAG-1 tended to have less favorable clinical outcome (see page 1716, last paragraph), and Yawata et al. teach that overexpression of BAG-1 increases the metastatic potential of gastric cancer cells and melanoma cells *in vivo*. Furthermore, it would have been obvious to one skilled in the art to substitute one method (such as immunohistochemistry taught by Froesch and Tang) for another (such as immuno-PCR taught by Sano et al.) to achieve the predictable results of detection BAG-1 expression. One of ordinary skill in the art would have had a reasonable expectation of success to determine the level of BAG-1 protein expressed in prostate cancer using immuno-PCR, compare the level with a reference level and further correlate the results with the risk of tumor recurrence, tumor spread and survival in a patient suffering from prostate cancer because Froesch et al have detected BAG-1 protein in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, Tang et al. have shown that BAG-1 is overexpressed in the majority of invasive breast carcinomas, and in multivariate analysis, BAG-1 expression was significantly associated with shorter disease-free and overall survival (see abstract, Figures 3 and 4), Yawata et

al. have shown that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells *in vivo*.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643

/Christopher H Yaen/
Primary Examiner, Art Unit 1643